UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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| Charles E. Bille, III,<br><br>Plaintiff,<br><br>v.<br><br>Medica Health Plans of Wisconsin,<br><br>Defendant. | Court File No. _____<br><br><br><br>**COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

Plaintiff Charles E. Bille, III ("Mr. Bille"), by and through undersigned counsel, brings this Complaint against Defendant Medica Health Plans of Wisconsin ("Medica") as follows:

## Introduction

1. Mr. Bille brings this case against Medica for failing to honor the coverage obligations under its insurance plan by refusing to pay for a prescribed medical device that would allow its insured, Mr. Bille, a paraplegic, to safely walk again. Mr. Bille was paralyzed following an unfortunate accident. His paralysis confines him to a wheelchair, which causes him to suffer severe and constant pain, intense spasticity, loss of muscle mass, pressure sores, digestion issues, poor bowel and bladder function, constipation, lethargy, negative impact on quality of life, and psychological effects, including depression.

2. Mr. Bille's physician recommended, prescribed, and ordered that Mr. Bille be supplied with the ReWalk, an FDA-cleared, wearable, prosthetic robotic exoskeleton

that provides powered hip and knee motion to enable individuals with spinal cord injury ("SCI"), like Plaintiff, to stand upright, walk on different surfaces, and maneuver turns and obstacles. Mr. Bille submitted his doctor's prescription and medical evidence to the Defendant Insurer for pre-approval of the ReWalk device, but Medica denied the claim. Mr. Bille timely complied with every administrative hurdle required by his Insurer. As part of his appeals process, he submitted overwhelming evidence demonstrating the reasons his Insurer should fulfill its policy obligations and cover the prescription for this device, including evidence of the medical reasonableness and necessity of this treatment and device from his treating physician, his primary physical therapists, and from a Board Certified Neuro Surgeon and SCI expert. Remarkably, without rebutting, or even addressing, the substantial and overwhelming testimony, clinical studies, medical literature and other evidence demonstrating not only the medical necessity, but also the safety, effectiveness of the ReWalk, and coverage of the device by other insurers, Defendant Insurer consistently refused to reverse its improper coverage denial.

3. Accordingly, Mr. Bille brings this action as a result of the Defendant's refusal to cover the ReWalk, a device that is medically necessary to enable him to get out of his wheelchair to stand and walk again. Among other things, Mr. Bille is seeking restitution equal to the cost of the ReWalk—$95,000—and equitable relief ordering that Defendant approve the ReWalk as medically reasonable, necessary, and not experimental for the treatment of SCI, in addition to Plaintiff's attorney's fees, costs, and prejudgment interest.

## The Parties

4. Plaintiff, Mr. Charles E. Bille, III lives at 4660 Allendale Drive, St. Paul, MN 55127-2324. He is an aspiring architect and is enrolled full-time in a local university's architecture program.

5. Upon information and belief, Defendant, Medica, a subsidiary of Medica Holding Company, is a Minnesota health insurance company that pays for benefits under and administers Plaintiff's health insurance plan (the "Plan") to which Mr. Bille has subscribed. A copy of the Plan's policy of coverage handbook (the "Handbook") is attached hereto as Exhibit A. Defendant is both the insurer liable for any benefits under the Plan and the claims administrator and fiduciary of the Plan.

6. Defendant is referred to as providing "claims administrative services" within the Plan's Handbook.

7. The ReWalk exoskeleton for which Mr. Bille seeks coverage is manufactured by ReWalk Robotics Ltd. (formerly Argo Medical Technologies Ltd., Marlborough, MA, USA) ("ReWalk Robotics"). The ReWalk is a prosthetic device designed for people with paraplegia, a spinal cord injury resulting in complete or incomplete paralysis of their legs. The system uses patented motion sensing technology along with battery-powered motorized legs to power knee and hip movement which is controlled by proprietary on-board computers and software.

## Jurisdiction and Venue

8. This Court has jurisdiction over this action pursuant to 29 U.S.C. §§ 1132(e)(1) and (f) and 28 U.S.C. § 1331.

9. Venue is proper in this District pursuant to 29 U.S.C. § 1132(e) because the breach took place in this District and the Defendant resides in this District.

**The Health Insurance Contract**

10. Plaintiff formerly worked in commercial construction, and is enrolled in the Plan.

11. Plaintiff is covered by the Plan and paid the Plan's premium, as required.

12. In exchange for Plaintiff's premium payments, Medica agreed to pay for all of Plaintiff's medical treatments and services that are medically reasonable and necessary and meet the Plan's guidelines.

13. Pursuant to the Plan's Schedule of Payments for 2016-2017, Durable Medical Equipment and Prosthetics are covered by Defendant Insurer with a zero percent in-network coinsurance and 50 percent out-of-network coinsurance by the Plaintiff.[1]

14. According to the Plan's Durable Medical Equipment ("DME") Used in the Home Setting Policy ("DME Policy"), attached hereto as Exhibit B, medical equipment prescribed by a physician that meets each of the following requirements is covered by the Plan when the device: (1) is prescribed for a defined medical purpose; (2) is determined to be reasonable and necessary; (4) is not generally useful in the absence of illness or injury; (5) has the ability to withstand repeated use; (6) is appropriate for use in the home setting; and (7) represents the most cost-effective care alternative (*e.g.*, assists in

[1] *See* Exhibit A at 77 (Medica Individual Choice, Minnesota Policy of Coverage Gold Copay 100 Plan, at 72).

preventing a higher level of care, as in home care versus skilled nursing facility or inpatient admission).[2]

15. The Plan's DME Policy also references the Plan's "DME Numeric Code List – Coverage Eligibility by Medica Product" (DME List), attached hereto as Exhibit C. Importantly, the Plan's DME List expressly provides positive coverage eligibility for all exoskeletal lower extremity prosthesis, like the ReWalk, under Plaintiff's Individual and Family Business ("IFB") benefits.[3]

**Plaintiff's Injury**

16. On August 17, 2014, Mr. Bille was injured in a tragic fall from a deck. Mr. Bille suffered a spinal cord injury that left him paralyzed in both legs. Prior to the accident, Mr. Bille was an able-bodied, active athlete. He exercised regularly, ran marathons, and participated in watersports.

17. From August 2014 to the present, Mr. Bille's paralysis has confined him to a wheelchair for 14-16 hours per day and he is unable to walk.

18. As a result of his wheelchair confinement, as Mr. Bille explained to Defendant Insurer, he experiences chronic pain and muscle spasticity. The prolonged confinement in his wheelchair has also caused Mr. Bille to experience poor bowel and bladder functions, loss of muscle mass, and at times, pressure sores.

[2] *See* Exhibit B at 3 (Medica Durable Medical Equipment (DME) Used in the Home Setting Policy).
[3] *See* Exhibit C at 270 (DME Numeric Code List – Coverage Eligibility Medica Product).

19. In addition to physical pain and discomfort, Mr. Bille suffers from lethargy and negative psychological symptoms and depression due to his wheelchair confinement, resulting in a decreased quality of life.

**The Treating Physician's Prescription**

20. In light of the physical and psychological ailments caused by Plaintiff's particular SCI, paralysis, and wheelchair confinement, Plaintiff's physician, Dr. Keith A. Moench of HealthPartners Physical Medicine and Rehabilitation, a specialist in physical medicine and rehabilitation, determined that Mr. Bille would benefit greatly from home use of the ReWalk.[4]

21. The ReWalk is a wearable motorized prosthetic device designed to act as an exoskeleton for people, like the Plaintiff, with lower body paralysis due to SCI. The ReWalk allows people with such injuries to stand up and walk again. The device provides powered hip and knee motion to enable individuals with SCI, like Mr. Bille, to sit, stand upright, and walk on different surfaces and maneuver turns and obstacles.[5] ReWalk users can autonomously determine walking initiation, speed, and direction through a combination of controller commands and shifts in body weight.[6] The ReWalk

[4] *See, e.g.*, Exhibit D (Exhibit 4 of External Request – Dr. Moench's Letters dated May 8, 2015 and Oct. 27, 2015); *see also* Exhibit D (Exhibits 15 of External Request – Declaration of Dr. Moench dated Dec. 18, 2015).
[5] *See, e.g.*, Exhibit D (Exhibits 4 and 15 of External Request); *see also* Exhibit D (Exhibit 16 - Declarations of Greta Wolf, DPT ("Wolf Decl."); Exhibit 17 – Declaration of Lindsay Olson, DPT ("Olson Decl."); Exhibit 20 – Declaration and Curriculum Vitae. of Dr. Vanni)).
[6] *See* Exhibit D (Exhibit 22 of External Request - Mary Beth Schmidt, *Medical Benefits of Computerized Exoskeleton Devices for Patients with Spinal Cord Injury*, Rewalk Robotics, Ltd., July 7, 2015, at 2).

can be used by individuals at home and in the community and allows users, like Plaintiff, to return to activities of daily living.[7]

22. ReWalk is one of two FDA-cleared exoskeleton systems for rehabilitation and personal use in the United States.

23. On May 8, 2015 and October 27, 2015, the Plaintiff's treating physician, Dr. Moench, submitted letters to Defendant Insurer (the "Prior Authorization Request")[8] requesting prior authorization for insurance coverage of the ReWalk he had prescribed and ordered for Plaintiff. Dr. Moench explained to the Defendant that Mr. Bille would benefit medically from the ReWalk because it would allow him to no longer be confined to his wheelchair for extended periods of time. Dr. Moench stressed to the Defendant that the ReWalk would promote Plaintiff's overall fitness, as well "reduce the clinical risks associate with inactivity." Dr. Moench concluded that Mr. Bille was an "excellent candidate" for the ReWalk and that the device was "medically necessary."[9]

24. In advance of Dr. Moench's prior authorization request, Mr. Bille already had demonstrated that he was able to use the ReWalk throughout multiple training sessions beginning in March 2015. Mr. Bille's training included three intensive two-day rehabilitation sessions at Regions Hospital's Courage Kenny Rehabilitation Institute in St. Paul, Minnesota (video and pictures of Plaintiff using the Rewalk can be found at Exhibits 7 and 19 of the External Request, enclosed in Exhibit D attached hereto). Mr. Bille demonstrated he was able to transfer into the ReWalk, perform sit-to-stand

[7] *Id.*
[8] *See supra* note 4.
[9] *Id.*

transitions with ease, and ambulate with forearm crutches on level surfaces up to 200 feet with improved endurance and ability to use one crutch to ambulate with minimal assistance.

25. Following his training sessions with the ReWalk, Dr. Moench and Plaintiff's physical therapists explained to Defendant that Mr. Bille experienced significant positive health outcomes with his use of the ReWalk. The ability to stand and ambulate with the ReWalk allows Mr. Bille to stretch the spinal column and helps decrease his pain. Improved pain management in turn allows Mr. Bille to participate more fully in the activities of daily living. In addition to decreased pain, Mr. Bille and his physician and physical therapists further explained to Defendant that Plaintiff also has experienced *decreased* muscle spasticity, better sleep and improved muscle tone using the ReWalk.[10] Plaintiff also reported *improved* bowel and bladder function following his use of the ReWalk. Mr. Bille further reported that he experienced positive psychosocial benefits standing and walking in the ReWalk as well, including improving his self-esteem. Plaintiff's physician and physical therapists also stressed that Plaintiff's use of the ReWalk at home would reduce his high risk of osteoporosis and megacolon (dilated large bowel) and toxic megacolon, a potentially fatal complication of chronic colonic dilation as well as diminish the likelihood of early-onset arthritis due to the repetitive power-stroke of the arms and shoulders required for Plaintiff's manual wheelchair use.[11]

[10] *See supra* note 6. *See also, e.g.*, Exhibit D, External Request (Exhibits 16 - Wolf Decl.; Exhibit 17 – Olson Decl.; Exhibit 18 - Sept. 2, 2015 Letter from Great Wolf, DPT and Lindsay Olson, DPT; Exhibit 20 – Declaration and Curriculum Vitae. of Dr. Vanni).
[11] *Id.*

**Defendant's Improper Denial of Treatment for Plaintiff**

26. On March 9, 2016, Defendant denied Plaintiff's prior authorization requests ("Prior Authorization Denial"), asserting without any support that the ReWalk Exoskeleton was "not covered by this patient's policy, as per medical director review."[12]

27. Plaintiff timely appealed Defendant Insurer's prior authorization denial pursuant to Defendant's internal appeals process. Dr. Moench submitted a first-level appeal on behalf of Mr. Bille on March 20, 2016 (the "Internal Appeal")[13], rebutting Defendant Insurer's denial by providing Defendant with clinical evidence demonstrating the medical necessity of the ReWalk. Dr. Moench attested to "the efficacy of the ReWalk powered exoskeletal orthotic walking system" and stated "there is ample peer-reviewed literature to show that [the] ReWalk is useful in reestablishing a gait pattern in individuals with paraplegia."[14]

28. On May 10, 2016, Defendant Insurer denied Mr. Bille's first-level internal appeal ("Internal Appeal Denial" or the "Denial")[15]. The denial stated that an unidentified "licensed nurse and a Medica physician advisor" examined Mr. Bille's appeal and upheld Defendant Insurer's initial coverage denial. Defendant asserted, without providing any clinical or other support, that "the ReWalk exoskeleton is not medically necessary" and that "there is insufficient evidence in the literature at this time to support the proposed secondary benefits, or the superiority of the device over more

[12] *See* Exhibit D (Exhibit 5 of External Request – Mar. 9, 2016 Letter from Medica).
[13] *See* Exhibit D (Exhibit 6 of External Request – Mar. 20, 2016 Letter from Dr. Moench).
[14] *Id.* at 3.
[15] *See* Exhibit D (Exhibit 3 of External Request – May 10, 2016 Letter from Medica).

standard rehabilitation approaches . . . . " Defendant identified the applicable policy as the "Experimental/Investigative services" of Plaintiff's policy.[16]

29. On August 10, 2016, Plaintiff timely requested an independent external review by an Independent Review Organization of the Defendant's coverage denial (the "External Request") as coordinated by the Minnesota Department of Commerce. A copy of the External Request is attached hereto as Exhibit D.

30. In the External Request, Mr. Bille submitted a signed declaration from Dr. Moench ("Moench Decl.")[17], who confirmed his professional medical opinion that Mr. Bille is "an excellent candidate for ReWalk" and that he prescribed the ReWalk based on "Mr. Bille's demonstrated enthusiasm to accomplish any task set before him."[18] Dr. Moench also opined that "the ReWalk Personal Exoskeleton System is medically necessary and reasonable for the health and wellbeing of Mr. Bille because the ReWalk would significantly improve Mr. Bille's constant pain and spasticity due to his wheelchair confinement."[19]

31. The External Request also included a sworn Declaration from an independent physician with special expertise in spinal cord injuries, Dr. Steven Vanni, a Board-Certified Neuro Surgeon and the Division Chief of Spinal Neurosurgery at

[16] *Id. at 2.*
[17] *See* Exhibit D (Exhibit 15 of External Request – Declaration of Dr. Moench dated Dec. 18, 2015).
[18] *See* Exhibit D (Exhibit 4 of External Request – Dr. Moench's May 8, 2015 Letter at 3).
[19] *See supra* note 15, ¶ 14.

Jackson Memorial Hospital in South Florida ("Vanni Decl.").[20] In his Declaration, Dr. Vanni opined that in his professional medical opinion, based on his review of information regarding the ReWalk, the most current published, clinical literature on SCI and the ReWalk, and Mr. Bille's medical records obtained from his treating physician and physical therapist, that the "ReWalk is medically necessary and beneficial for the Plaintiff's use at home."[21]

32. On August 18, 2016, the Minnesota Department of Commerce deemed the Plaintiff eligible for external appeal and notified Plaintiff that the agency was forwarding Mr. Bille's External Request and materials to a third party independent review entity selected by the State to review external appeals. A copy of the Letter for External Appeal is attached hereto as Exhibit E.

33. On October 5, 2016, Plaintiff received a written decision by Maximus (the "Maximus Decision")[22], the independent reviewer, upholding Defendant's denial of coverage for Mr. Bille repeating Defendant's assertion that the ReWalk was "investigational." Notably, the Maximus Decision did not address the signed declarations of support submitted by Plaintiff's treating physician and physical therapists, nor did Maximus specifically address, or even attempt to respond to, much less refute, the signed, sworn Declaration submitted by Dr. Vanni or the clinical studies and other

[20] *See* Exhibit D (Exhibit 20 of External Request – Declaration of Dr. Vanni dated Dec. 17, 2015 and Curriculum Vitae).
[21] *Id.*
[22] *See* Exhibit F – Maximus Decision dated October 5, 2016.

medical literature and evidence cited by Plaintiff in the External Request demonstrating that the ReWalk is safe, effective and medically necessary for Mr. Bille.

34. The Maximus Decision cited to some studies in support of its conclusion that the ReWalk is investigational.[23] However, many of these studies are out of date and, notably, all of the studies cited by Maximus *do support* the safety, effectiveness and long-term benefits of the ReWalk, as well as its medical necessity and appropriateness for patients with SCI like the Plaintiff's.

35. Indeed, one of the purported grounds upon which Maximus upholds Defendant Insurer's denial is that "a review of the literature does not reveal that the requested ReWalk exoskeletal system provides greater benefit for the member's condition over the current standard of care for patients with this type of spinal cord injury."[24] However, unlike the ReWalk, traditional rehabilitation therapies such as the use of a standing frame, do not allow patients to ambulate at home or in community settings. Thus, such devices would not be effective in relieving or reducing Mr. Bille's wheelchair confinement and negative health effects that confinement causes.

36. In affirming Defendant's coverage denial, the Maximus Decision also failed to address the *most current* clinical studies, including a recently-published systematic review and meta-analysis study ("Miller 2016")[25] submitted in Mr. Bille's

[23] *Id.* at 4.
[24] *Id.* at 3.
[25] *See* Exhibit D (Exhibit 23 of External Request - Miller, L. et al. "Clinical effectiveness and safety of powered exoskeleton assisted walking in patients with spinal cord injury: systematic review with meta-analysis." Medical Devices: Evidence and Research. 2016:9 1-12).

External Request, which reviewed 14 published studies on robotic exoskeleton therapy for SCI patients like Mr. Bille. These 14 studies, which were all published within the last four years, cover a total of 111 male and female patients. The Miller 2016 study analyzed the published clinical literature to assess the clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with SCI. The 14 reviewed studies identified concrete health benefits from the use of a robotic exoskeleton, such as increased cardiac activity, improved bowel movements and improved muscle spasticity. The clinical benefits identified in these patients from the use of a robotic exoskeleton were significant and could not have been achieved by patients using conventional therapy, such as wheelchairs.[26]

37. As Plaintiff explained in his External Request, multiple independent/external review organizations have found the ReWalk to be safe and effective and not experimental or investigational, including Maximus – the very independent review organization that denied the ReWalk for the Plaintiff in this case. For example, in April 2016, Advanced Medical Reviews (acting as an External Reviewer) reversed a commercial insurer's determination that the ReWalk was experimental. The reviewer, a physician specializing in physical medicine and rehabilitation, summarized certain clinical literature and concluded, "[t]here is sufficient evidence of benefit found in current peer-reviewed medical literature to support the use

[26] *See id.*; *see also* Exhibit D (Exhibit 24 of External Request – Summary of Significant Studies).

of a ReWalk exoskeletal system in this member as cited in the peer reviewed literature."[27] The reviewer further determined that "[t]he use of a ReWalk exoskeletal system in members with spinal cord has been shown to be beneficial in numerous clinical trials in current evidence based medical literature."[28] Similarly, pursuant to a December 30, 2015 Peer Reviewer Final Report, a physician reviewer reversed another payor's determination that the ReWalk is "experimental." The reviewer concluded that "due to documented safety and benefit of the ReWalk system in patients with spinal cord injury, the requested ReWalk Device would not be considered experimental/investigational."[29] And, most recently, in an independent medical review completed by Maximus Federal Services, on June 15, 2016, two expert physicians found, based on a review of the clinical literature including peer-reviewed scientific and medical evidence, as well as the SCI patient's case file, that the ReWalk "is likely to be more beneficial than any available standard therapy."[30] In the Plaintiff's case, the same External Reviewer, Maximus, failed to address, much less refute, any of these recent external review decisions which reversed the insurers' coverage denials for the ReWalk.

38. In addition to independent/external review organizations, multiple commercial and government insurers have deemed the ReWalk safe and effective, and not experimental or investigational. For example, the U.S. Department of Veterans

[27] *See* Exhibit D (Exhibits 11-13 of External Request – Redacted Independent Medical Reviews dated April 6, 2016, December 30, 2015, and June 15, 2016).
[28] *Id.*
[29] *See* Exhibit D (Exhibit 12 of External Request - Redacted Independent Medical Review dated Dec. 30, 2015 at 2).
[30] *See* Exhibit D (Exhibit 13 of External Request - Redacted Independent Medical Review dated June 15, 2016).

Affairs ("VA") announced in a December 10, 2015 Memorandum[31] that it is making the ReWalk Powered Exoskeleton available to veterans with SCI who meet specified criteria. The VA has the largest single network of SCI care in the nation. The policy recognizes that the current published clinical data supports the safety and effectiveness of the ReWalk and the clinical benefits that stem from use of the ReWalk. The new policy will enable eligible veterans with SCI to train and use the ReWalk device.

39. State Medicaid agencies have also found the ReWalk to be medically necessary and not experimental. On December 9, 2016, for example, the ReWalk was approved for coverage by the Massachusetts Office of Medicaid Board of Hearings ("BOH").[32] The BOH reversed a coverage denial by a Medicaid Managed Care Plan for a Massachusetts Medicaid member who has a SCI similar to Mr. Bille. Following a live hearing, and after reviewing the evidence supporting the safe, effective and beneficial use of the ReWalk for SCI patients (including the most recent clinical medical studies cited by Plaintiff in this case), the BOH's Hearing Officer determined that the ReWalk is *not* experimental or investigational and *is* medically necessary under MassHealth regulations, which include Medicaid coverage guidelines similar to the standards cited by the Defendant Insurer and Maximus.[33]

[31] *See* Exhibit D (Exhibit 21 of External Request - Department of Veterans Affairs, Memorandum from Acting Deputy Under Secretary for Health for Operations and Management to Medical Center Directors, "Clinical Protocol for Veteran Use of the ReWalk™ Powered Exoskeleton" (December 10, 2015)).
[32] *See* Exhibit G – Redacted Massachusetts BOH Decision dated December 9, 2016.
[33] *See id.*

**Count I – Denial of Benefits (§ 502(a)(1)(B))**

40. Plaintiff realleges paragraphs 1-39 above, as if fully set forth herein.

41. Plaintiff and Defendant were parties to a valid and binding insurance plan in which Defendant agreed to pay for all of Plaintiff's medically reasonable and necessary treatments and services in exchange for Plaintiff's payment of premiums.

42. Plaintiff paid all premiums and complied with all conditions of the insurance plan.

43. Plaintiff suffered an injury that ultimately required treatment through prescribed home use of the ReWalk. Treating Plaintiff's injury through use of the ReWalk is medically reasonable and necessary as confirmed by his treating physician, Dr. Moench, his physical therapists, as well as by Dr. Vanni, a Board Certified Neurosurgeon and SCI specialist.[34]

44. Defendant is obligated to pay for medically reasonable and necessary treatments for Mr. Bille, including the ReWalk.

45. The ReWalk is safe and effective and not experimental or investigational under Mr. Bille's Plan policy. The ReWalk has been cleared by the FDA for home use and thus is not subject of review or approval by an Institutional Review Board for the proposed use, nor subject to Phase I-III clinical trials. As explained in Mr. Bille's External Request and supported by his treating clinicians and an independent expert in

[34] *See* Exhibit D (Exhibits 15-17, 20 of External Request – Declarations of Moench, Wolf, Olson, and Vanni).

SCI, the ReWalk is safe and effective under existing peer-reviewed, evidence-based, scientific literature for treating SCI.

46. Moreover, exoskeleton lower extremity prostheses, which would include the ReWalk, are explicitly covered by Defendant's Insurer's Plan for Mr. Bille pursuant to the Plan's DME List (enclosed as Exhibit C).

47. Plaintiff, through his treating physician, submitted a claim for prior authorization of the ReWalk to threat his SCI other conditions caused by his confinement to a wheelchair.

48. Defendant improperly refused to pay for Plaintiff's treatment through the ReWalk and denied Plaintiff's claim for coverage in violation of his rights to benefits under the applicable Medica plan.

49. As a result of Defendant's improper denial of benefits, Plaintiff has not received the needed treatment prescribed by his treating physician and supported by his physical therapists as medically necessary and beneficial to his health.

50. Defendant's improper denial of benefits continues to cause Plaintiff injury because, *inter alia*, Plaintiff continues to suffer from severe and painful medical symptoms due to wheelchair confinement which would be otherwise eliminated or reduced with treatment by the ReWalk.

**Count II – Failure to Fully and Fairly Review Claim (§ 503)**

51. Plaintiff realleges paragraphs 1-50 above, as if fully set forth herein.

52. Mr. Bille's primary physical therapists, Greta L. Wolf, DPT and Lindsay M. Olson, DPT, have confirmed in formal Declarations that the Plaintiff experiences

significant positive health outcomes with use of the ReWalk and described Plaintiff's progress and significant success with his use of the ReWalk in a rehabilitation setting.[35] Ms. Wolf and Ms. Olson further stated that they anticipate Mr. Bille would experience additional health benefits from use of the ReWalk on a consistent basis, including improvements to digestion and constipation, improvements in bladder function and bone density and overall improved physiological well-being.[36]

53. Existing clinical evidence also supports the safety and effectiveness of the ReWalk, which clinical evidence Plaintiff submitted to Defendants for their review and consideration.

54. Reviewing and considering the same clinical evidence to determine whether the ReWalk was safe, effective, and not experimental or investigational to treat people with similar injuries, multiple other insurers already have deemed the ReWalk to be safe, effective, and not experimental or investigational.

55. Defendant did not consider the declaration of Dr. Steven Vanni, a Board-Certified Neuro Surgeon and the Division Chief of Spinal Neurosurgery at Jackson Memorial Hospital in South Florida, which opined that in his professional medical opinion, based on his review of information regarding the ReWalk, the most current published, clinical literature on SCI and the ReWalk, and Mr. Bille's medical records

[35] Exhibit D (Exhibits 16-18 of External Request – Wolf Decl., Olson Decl., and their Sept. 2, 2015 Letter).
[36] *See id.*; *see also* Exhibit D (Exhibit 20 of External Request – Vanni Decl.).

obtained from his treating physician and physical therapist, that the "ReWalk is medically necessary and beneficial for the Plaintiff's use at home."[37]

56. Defendant Insurer failed to consider and did not consider the current clinical literature submitted as part of the External Request demonstrating the safety and effectiveness of the ReWalk for SCI patients.

57. The Defendant's DME Policy does not provide any basis for, or evidence supporting, Defendant's conclusion that the ReWalk is experimental/investigational. Rather, the policy simply provides criteria that the ReWalk squarely meets. Defendant and the External Review did not consider the recent studies (*e.g.*, Miller 2016) that Mr. Bille submitted throughout the appeal process. Moreover, Defendant's DME List expressly sets forth affirmative coverage of exoskeleton lower extremity prostheses (like the ReWalk) under Plaintiff's IFB Plan.[38]

58. As a result of Defendant's failure to fully and fairly review Plaintiff's claim, Plaintiff has not received the needed treatment prescribed by his treating physician and supported by his physical therapists as medically necessary and beneficial to his health.

59. Defendant's failure to fully and fairly review Plaintiff's claim continues to cause Plaintiff injury because, *inter alia*, Plaintiff continues to suffer from severe and painful medical symptoms due to wheelchair confinement which would be otherwise eliminated or reduced with treatment by the ReWalk.

[37] Exhibit D (Exhibit 20 of External Request – Vanni Decl.).
[38] Exhibit D (Exhibit 3 of External Request – Internal Appeal Denial).

**Count III – Breach of Fiduciary Duty/Knowing Participation (§ 502(a)(3))**

60. Plaintiff realleges paragraphs 1-59 above, as if fully set forth herein.

61. Defendant is a plan fiduciary who exercised discretionary control over the operation and administration of the plan. Defendant owes the plan beneficiaries fiduciary duties to truthfully represent facts and procedures, to consider beneficiaries interests impartially with the interests of the payor, and owe beneficiaries a fiduciary duty of care to consider their interests fully and fairly.

62. Defendant has a conflict of interest as both the payor and plan administrator. It breached its fiduciary duty to exercise care in making health care treatment decisions and coverage determinations by failing to fully and fairly review Mr. Bille's claim for benefits, improperly asserted its policy to support denial, which did not support denial, and rejected Plaintiff's challenge in a one-paragraph decision.

63. Defendant breached its fiduciary duty of loyalty and impartiality to its plan beneficiaries by considering its own interests and the interests of the payors above the interests of Plaintiff and other beneficiaries and their rights to benefits under the plan.

64. Defendant has profited from their breaches of fiduciary duty by reducing their payments for plan benefits to which Mr. Bille is entitled.

65. Defendant's breaches of fiduciary duty harmed Mr. Bille by depriving him of the benefits of the Plan, to which he is justly entitled.

66. Defendant's ill-gotten gains from its misrepresentations and breach of care/loyalty should be disgorged, Plaintiff is entitled to appropriate equitable relief including provision of the ReWalk, and Defendant is liable for Plaintiff's attorneys' fees.

**Count IV – Declaratory Judgment**

67. Plaintiff realleges paragraphs 1-66 above, as if fully set forth herein.

68. Defendant denied Plaintiff's repeated requests for pre-approval of coverage for the ReWalk treatment.

69. Mr. Bille's treating physician Dr. Moench,[39] independent expert Dr. Vanni,[40] and his treating physical therapists Greta L. Wolf, DPT and Lindsay M. Olson, DPT,[41] all submitted sworn declarations attesting to Mr. Bille's improvements through treatment and the medical reasonableness and necessity of the ReWalk.

70. The Defendant failed to review or address any of the above evidence, but nonetheless—in a *one paragraph* decision—denied Mr. Bille his proscribed treatment with the ReWalk.[42]

71. As a result of Defendant's denial, Plaintiff has not been able to receive his prescribed medical treatment.

72. A real, actual, and justiciable controversy exists between the parties.

73. An order from this Court declaring that the ReWalk is medically reasonable and necessary for the treatment of Plaintiff's injuries and symptoms would terminate the uncertainty and controversy giving rise to this proceeding.

[39] Exhibit D (Exhibit 15 of External Request – Moench Decl.).
[40] Exhibit D (Exhibit 20 of External Request – Vanni Decl.).
[41] Exhibit D (Exhibits 16-18 of External Request – Wolf Decl., Olson Decl., and their Sept. 2, 2015 Letter).
[42] Exhibit D (Exhibit 3 of External Request – Internal Appeal Denial).

WHEREFORE, Mr. Bille respectfully prays for the following relief: (a) restitution equal to the cost of the ReWalk, $95,000, (b) equitable relief ordering that Defendant approve the ReWalk as medically reasonable, necessary, and not experimental for the treatment of SCI, (c) attorney's fees and costs, (d) prejudgment interest, and (e) other relief that this Court deems just and equitable.

Dated: March 27, 2017

s/ Nicole M. Moen

Nicole M. Moen (#0329435)
**FREDRIKSON & BYRON, P.A.**
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425
Telephone: 612.492.7000
Facsimile: 612.492.7077
nmoen@fredlaw.com

***Attorneys for Plaintiff***